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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,551	01/30/2002	Shie-Ming Hwang	1224-005	2024

7590 01/14/2004

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,551	HWANG, SHIE-MING	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

New claims 8-15 are pending and under examination. [10/21/2003].

Claims 1-7 are cancelled by applicant.

Claim Objections

New claims 8-15 are objected to because of the following informalities:

New claim 8 contains several typing errors: missing letters in words "detector" and "minutes"; missing coma at the end of the claim; missing letter "e" for identification of characterization following "d)". Appropriate corrections are required.

Claim Rejections - 35 USC § 112

New claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites the limitation drawn to characterization of the claimed components by Figures 3A and 3B in the method of using the component made as encompassed by claim 8. However, the Figures 3A and 3B demonstrate the HPSEC profiles of the component (see specification page 11, par. 1). But the preparation and characterization of the component in the preceding claim 8 is drawn to the use of the HPLC analysis and preparation that comprises different column, different mobile phases and different run time that the HPSEC preparations (see specification page 22, lines 5-19). Thus, there is insufficient antecedent basis for this limitation drawn to the reference to Figures 3A and 3B in the claim 9.

For the claim language it is suggested to use references to the figures that demonstrate the component profiles relative to the acetaminophen control peak as in the allowed patent US 5,776,462; for example: figures 2A and/or 2B.

Double Patenting

Applicants' intention to file Terminal Disclaimer is acknowledged (see response filed 10/21/03 at page 5].

New claims 8-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,776,462 for the same reasons as explained in the prior office and below.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the similar methods of inhibiting attachment of *H.influenza* by administering a composition comprising effective amount of a component derived from an aqueous extract of *Pogostemon cablin.* The scope of the component/extract in the claims of the instant application and of the extract of the patented claims is identical regardless the fact that claims refer to different figures. The figures 1, 2, 3 and 4 demonstrate profiles of the same extract "P10E" which is an aqueous extract of *Pogostemon cablin.*

Some of the claims the patent US 5,776,462 are drawn to the effective amount or dose at least 0.4 gms per day as related to the aqueous extract of *Pogostemon cablin.* This dose is the same or it is within the range that is presently claimed (see instant claims 8 and 11). The conflicting claims encompass the same route of administration and forms of the compositions as related to the aqueous extract of *Pogostemon cablin.*

Accordingly, the claimed methods are obvious variants. Thus, the inventions as claimed are co-extensive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

New claims 8-15 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 08176002 [Form PTO-892 mailed 4/22/2003, reference P].

Claims are directed to a method of inhibiting attachment of *H.influenza* to human cells wherein the method comprises one active step of administering to a human patient from 0.01 to 20 grams of a composition comprising component(s) derived from an aqueous extract of *Agastache rugosa*. Some claims are further drawn to administration of the amount of at least 0.04 gms per day, to the oral or nasal route of administration or to the forms of the compositions including tablet, jelly and etc. in the method for administration.

JP 08176002 teaches a method of preventing and treating cell adhesion or pathogenic cell attachment wherein the method comprises one active step of administering to a patient from 20 to 500 mg/kg/day {or 0.12-30 grams for a human patient having weight of about 60kg} of a therapeutic composition comprising active ingredients of an aqueous extract of *Agastache rugosa* (see English abstract; or see official translation page 4, par. 0012; page 3, par. 0007; page 4, par. 0009, line 2; page 4, par. 0010, line 2; page 5, par. 0017). The cited patent teaches oral and topical or nasal routes of administration of the therapeutic composition. The cited patent

teaches various forms of the therapeutic composition including tablets, gels and sprays (translation par. 0012 and 0014).

Therefore, the cited patent JP 08176002 teaches the use of the same effective amounts of the same composition in the one active step method of administering. Thus, the effects of the cited method as reasonably expected to be the same as intended for the presently claimed method as result of practicing identical protocol of administration. Moreover, the cited patent teaches that therapeutic effects of the active ingredients derived from the aqueous extract of *Agastache rugosa* are related to inhibiting of cell adhesion and to the anti-inflammatory/anti-allergy effects and to alleviation of upper respiratory tract distress. Although the cited patent teaches a method for administration that encompasses treatment of a general human patient regardless the patent age, the treatment of an infant would reasonably be within the same scope as disclosed and as presently claimed particularly with respect to the broad dosage ranges as claimed and as disclosed.

Therefore, the cited patent JP 08176002 is considered to anticipate the presently claimed invention.

Response to Arguments

Applicant's arguments filed 10/21/2003 have been fully considered.

Claim rejections over CN 1078399 [O] are withdrawn because the cited document does not teach protocol of administration including the same effective doses of the therapeutic composition in the method for administration for human patients as presently claimed and it does not suggest effects related to inhibiting attachment of *H.influenza* in the method for administration of the composition comprising aqueous extract of *Agastache rugosa*. Applicant's

argument drawn to the use of ethanol extract (response page 5) is not found particularly convincing since the ethanol extracts of plant materials are also aqueous extracts at least to some extend with regard to the materials used and to the components extracted.

The reference CN 1063796 [N] is not applied to the instant claims because the cited document neither teaches effective doses of the therapeutic composition nor it suggests effects related to inhibiting attachment of *H.influenza* in the method for administration of the therapeutic composition comprising aqueous extract of *Agastache rugosa*. Applicant's argument drawn to the use of three (3) specific components derived from *Agastache rugosa* (response page 7) is not found particularly convincing since the presently claimed method encompasses the use of the whole extract by the virtue of the language "comprising" as related to the use of the therapeutic composition.

With respect to the patent JP 08176002 applicant appears to argue that the active ingredients of the therapeutic compositions of the cited patent are extracted with water or various organic solvents (response page 6, par. 3). However, the cited patent clearly teaches alternative use of water for making plant extract (see translation page 4, par. 009, line 2). Thus, the same active ingredients or components are reasonably expected to be within the therapeutic composition comprising aqueous extract of *Agastache rugosa* of the cited patent. The presently claimed composition **is not limited** to the use of specific component(s) by the virtue of the claim language "comprising" as related to the use of the therapeutic composition. The component(s) as claimed are within the whole aqueous extract of *Agastache rugosa* that used for administration the therapeutic method of the cited patent JP 08176002.

Applicant further argues that the cited patent JP 08176002 is concerned with the cancerous cell attachment (response page 6, last par.). This argument is not found convincing because the cited patent discloses the use of cancerous cells as a human cell model to demonstrate the cell attachment inhibiting effects of the therapeutic composition. The cited patent clearly teaches the method of administration as explained above. The cited patent teaches the anti-inflammatory effects of the composition comprising aqueous extract of *Agastache rugosa* including treatments of upper respiratory distress, for example. It is known in the prior art that the respiratory distresses are caused by adherence of *Haemophilus influenza* to nasal, nasopharyngeal and buccal epithelial cells of patients with otitis media, for example: see abstract of the reference by Harada et al. {European Archives of Otorhinolaryngology (1990), pages 247122-124.}. Thus, the inherent effects of the composition of the cited patent JP 08176002 are reasonably expected to provide for effects including inhibiting attachment of *H.influenza* to human cells upon administration of the composition in the method of JP 08176002 within the same scope as disclosed and as presently claimed.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351 till January 15, 2004 or (571) 271-0914 after January 15, 2004. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743 till January 15, 2004 or on (571) 272-0926 after January 15, 2004.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

January 9, 2004

V. Afremova

VERA AFREMOVA

PATENT EXAMINER